

STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:)	
)	
FAMILY ENTERPRISES, INC. d/b/a)	Complaint No. 2010-002492
SUPER SAVER DISCOUNT PHARMACY)	
Highway 53 and South Broadway)	
Poplar Bluff, MO 63901)	

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF
PHARMACY AND FAMILY ENTERPRISES, INC.
d/b/a SUPER SAVER DISCOUNT PHARMACY**

Come now Family Enterprises, Inc. d/b/a Super Saver Discount Pharmacy ("Respondent" or "Super Saver") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and

voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 004525, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent, Family Enterprises, Inc. d/b/a Super Saver Discount Pharmacy ("Super Saver" or "Respondent"), located at Highway 53 & South Broadway, 449 Highway 53 in Poplar Bluff, Missouri is permitted as a pharmacy under the laws of the State of Missouri, Permit No. 004525. Respondent's permit was at all times relevant herein, current and active.

3. At the times pertinent herein, David Wendel, R.Ph. was pharmacist-in-charge of Family Enterprises, Inc. d/b/a Super Saver Discount Pharmacy.

4. On or about March 4, 2010, Inspector Mike Kidd sent written correspondence to the Board advising that Respondent had sustained a large loss of controlled substances allegedly

due to employee theft.

5. On March 4, 2010, the Board assigned Inspector Kidd to conduct an investigation into Respondent's controlled substance losses. The investigation was assigned Complaint No.: 2010-002492.

6. Inspector Kidd prepared a Memorandum dated March 12, 2010 which was received by the Board on March 15, 2010.

7. Inspector Kidd conducted an investigation and prepared an Investigation Report dated March 28, 2010 which was received by the Board on April 2, 2010.

8. The Board met at its regularly scheduled meeting in April of 2010 to review investigative information and allegations concerning the acts and conduct of Respondent.

9. Based upon its review, the Board, pursuant to Section 338.055, RSMo, concluded Respondent engaged in conduct which would be grounds for disciplinary action by the Board.

**Failure to Protect Against
Loss of Controlled Substances and Drug Diversion**

10. At the times pertinent herein, D.W. was pharmacist-in-charge of Family Enterprises, Inc. d/b/a Super Saver Discount Pharmacy.

11. Pharmacy Technician, R.L.T. was employed by Respondent for approximately ten (10) years including January 7, 2009 through January 20, 2010.

12. On or about January 18, 2010, Respondent's staff (pharmacy technicians, S.W., L.B. and R.M.) noticed a 100 count stock bottle of Hydrocodone/APAP 10/650 either missing or misplaced from the pharmacy's inventory.

13. Per Respondent's company policy, all pharmacy staff were required to submit to a

twelve (12) drug urine test on January 20-21, 2010. Staff urine tests were administered and processed by Pharmatech Laboratories for further analysis.

14. On January 21, 2010, Respondent's pharmacy technician, R.L.T. admitted to consuming controlled substance medications for which she had no prescription. R.L.T. was placed on administrative leave pending the outcome of drug testing.

15. PIC D.W. initiated an internal audit to assess the situation and extent of loss, if any.

16. On January 22, 2010, R.L.T. provided a handwritten statement wherein she admitted to taking Hydrocodone and Xanax from the Respondent pharmacy, her grandmother, and others; but did not admit to taking the 100 count stock bottle of Hydrocodone/APAP 10/650 either missing or misplaced from the pharmacy's inventory.

17. On February 22, 2010, the urine sample submitted by Respondent's pharmacy technician R.L.T. tested positive for Hydrocodone and Butalbital.

18. Hydrocodone/APAP is a Schedule III controlled substance.

19. Butalbital is a Schedule III controlled substance.

20. After R.L.T.'s confession, Respondent's PIC, D.W., asked Respondent's staff to conduct an internal audit of nineteen (19) drugs held for sale as part of Respondent's controlled substance inventory. The audit was conducted by Respondent's pharmacy technicians, E.H. and S.W. and was completed on or about March 3, 2010.

21. On March 4, 2010, the Pharmacy filed a Form 106 with DEA, BNDD and the Missouri Board of Pharmacy notifying them of missing controlled substances.

22. On or about March 4, 2010, Inspector Kidd received a phone call from Respondent's PIC, D.W., that a pharmacy technician R.L.T. had signed a written statement

acknowledging her theft of controlled substance medications from Respondent's pharmacy located at Highway 53 & So. Broadway in Poplar Bluff, Missouri.

23. Inspector Kidd interviewed Respondent's PIC, D.W., R.Ph., on March 4, 2010 by telephone.

24. D.W. advised Inspector Kidd that he had commissioned an audit of controlled substances at the Respondent pharmacy and Respondent's pharmacy staff had identified the following shortages:

Drug	Shortage
Hydrocodone/APAP 10/650 mg	13,789 tablets
Hydrocodone/APAP 10/500 mg	6789 tablets
Hydrocodone/APAP 10/325 mg	6416
Hydrocodone/APAP 7.5/325 mg	358 tablets
Hydrocodone/APAP 5/325 mg	633 tablets
Diazepam 10mg	686 tablets
Diazepam 5 mg	908 tablets
Diazepam 2 mg	80 tablets
Clonazepam 2 mg	40 tablets
Clonazepam 1 mg	6846 tablets
Clonazepam 0.5 mg	2658 tablets
Alprazolam 1 mg	3168 tablets
Xanax 1 mg	400 tablets
Alprazolam 0.5 mg	411 tablets

Butalbital/APAP/Caf	450 tablets
Butalbital/APAP/Caf/codeine	120 tablets
Butalbital/APAP/Caf	4880 tablets
Phentermine 37.5 mg	100 tablets
Phentermine 30 mg	670 tablets
TOTAL:	49,402 tablets short

25. Respondent's PIC, D.W., faxed an itemized listing of the above referenced losses to Inspector Kidd.

26. Hydrocodone/APAP is a Schedule III controlled substance.

27. Diazepam is a Schedule IV controlled substance.

28. Clonazepam is a Schedule IV controlled substance.

29. Alprazolam, a.k.a Xanax, is a Schedule IV controlled substance.

30. Butalbital is a Schedule III controlled substance.

31. Phentermine is a Schedule IV controlled substance.

32. Respondent filed a Report of Loss or Theft of Controlled Substances dated March 4, 2010 with the Bureau of Narcotics and Dangerous Drugs ("BNDD") which acknowledges the losses of controlled substances identified in paragraph 23 above.

33. Respondent also filed a Report of Theft or Loss of Controlled Substances dated March 4, 2010 with the Drug Enforcement Agency ("DEA") which acknowledges the following losses of controlled substances due to employee pilferage:

Drug	Shortage
Hydrocodone/APAP 10/650 mg	13,789 tablets
Hydrocodone/APAP 10/500 mg	6789 tablets
Hydrocodone/APAP 10/325 mg	4616** (Under-reported. BNDD Report states 6416 tablets were lost)
Hydrocodone/APAP 7.5/325 mg	358 tablets
Hydrocodone/APAP 5/325 mg	633 tablets
Diazepam 5 mg	908 tablets
Diazepam 2 mg	80 tablets
Clonazepam 2 mg	40 tablets
Clonazepam 1 mg	6846 tablets
Clonazepam 0.5 mg	2658 tablets
Alprazolam 1 mg	3165** (Under-reported. BNDD report says 3168 tablets missing.
Xanax 1 mg	400 tablets
Alprazolam 0.5 mg	411 tablets
Butalbital/APAP/Caf/codeine	120 tablets
Phentermine 37.5 mg	100 tablets
Phentermine 30 mg	670 tablets
Alprazolam 0.25 mg	1,245 tablets

34. In its March 4, 2010 Report to DEA, Respondent under-reported the loss of two controlled substance medications to wit:

Alprazolam 1 mg	3165** (Under-reported. BNDD report says 3168 tablets missing.
Hydrocodone/APAP 10/325 mg	4616** (Under-reported. BNDD Report states 6416 tablets were lost)

35. In its March 4, 2010 Report to DEA, Respondent failed to report a loss of the following controlled substances which were reported to the BNDD:

Diazepam 10mg	686 tablets ** didn't report to DEA
Butalbital/APAP/Caf	450 tablets **didn't report to DEA
Butalbital/APAP/Caf	4880 tablets ** didn't report to DEA

36. On March 4, 2010, Inspector Kidd contacted the Drug Enforcement Agency, ("DEA") and scheduled a meeting with DEA investigators, Brian Hudson, Tim Dixon, and Dave Tetamble, Respondent's PIC, D.W., and Respondent's former pharmacy technician, R.L.T.

37. Inspector Kidd was informed that R.L.T. would be arrested on March 10, 2010.

38. Inspector Kidd responded to the Poplar Bluff, Missouri Police Department on or about March 9, 2010 to conduct a joint videotaped interview with Respondent's pharmacy technician, R.L.T.

39. On or about March 9, 2010, R.L.T. admitted to stealing Hydrocodone, Diazepam and Alprazolam from Respondent's pharmacy beginning in November of 2008 through January 19, 2010.

40. R.L.T. admitted that she initially took approximately 30-40 pills per week and occasionally, a 100 count stock bottle of controlled substance medication without being detected. Her thefts then escalated to approximately 100 pills per day, four to five days per week.

41. R.L.T. provided a written statement to Inspector Kidd on or about March 9, 2010 in which she admitted the theft of Hydrocodone, Diazepam and Alprazolam from Super Saver Discount Pharmacy.

42. R.L.T. denied taking Phentermine or Clonazepam from Respondent's pharmacy.

43. R.L.T. voluntarily surrendered her pharmacy technician registration to Inspector Kidd and was then arrested on March 9, 2010 by the Drug Enforcement Agency ("DEA").

44. In total, Respondent – by and through its business records and statements of its employees and authorized agents, acknowledges the loss of approximately 50,747 tablets of controlled substance medications between January 7, 2009 and January 30, 2010; only *some* of which can be attributed to theft by pharmacy technician R.L.T.

45. R.L.T. estimates that her thefts began in November of 2008, which pre-dates the audit performed by Respondent referenced above.

46. Respondent knew or should have known that violations of pharmacy laws or rules had occurred including the theft or diversion of large quantities of controlled substances over the course of more than fourteen (14) months.

Statutes and Regulations Violated

47. Respondent was and continues to be responsible for complying with all state and federal laws pursuant to Section 338.250 RSMo. which states, in part, that:

"...Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as state and federal drug laws on all drugs received or possessed, including, but not limited to drugs and devices received or possessed pursuant to a consignment arrangement". §338.250 RSMo. (2000).

48. 19 CSR 30-1.031(1)-(2) states as follows:

"(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032-19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.

(2) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly." 19 CSR 30-1.031 (1)-(2).

49. From approximately November 2008 through January 30, 2010, Respondent failed to implement effective security controls for its scheduled controlled substances.

50. 21 CFR 1301.71(a) states as follows:

"(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections." 21 C.F.R. § 1301.71(a).

51. 20 CSR 2220-2.010(1)(H) states as follows:

"(H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility." 20 CSR 2220-2.010 (1)(H).

52. From approximately November 2008 through January 30, 2010 Respondent failed to provide effective security controls and procedures to guard against theft and diversion of

schedule II through V controlled substances.

53. Respondent's conduct herein described is in violation of §338.250 RSMo. (2000), 19 CSR 30-1.031 (1)-(2), 21 C.F.R. § 1301.71(a) and 20 CSR 2220-2.010 (1)(H).

JOINT CONCLUSIONS OF LAW

54. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under 20 CSR 2220-2.010(1)(O) which states:

"(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo." 20 CSR 2220-2.010(1)(O).

57. Cause exists for Petitioner to take disciplinary against Respondent's pharmacy permit under Section §338.285, RSMo, which states:

"The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055." Section 338.285 RSMo. (2000).

58. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under §338.055 RSMo. (2000) which provides,

"2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any

combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;" §338.055 RSMo. (2000).

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

1. Respondent's permit to operate a pharmacy shall be placed on **PROBATION** for a period of three (3) years. The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

A. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

B. Respondent shall comply with all provisions of Chapter 338, Chapter 195 and all applicable federal and state drug laws, rules, and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by Respondent, and the individuals' current home addresses and telephone numbers.

D. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1, and July 1), beginning with whichever date occurs first after this Order / Agreement becomes effective, stating truthfully whether or not the pharmacy has complied with all terms and conditions of this disciplinary order.

F. Respondent shall not serve as an intern training facility for interns.

G. Respondent shall select an independent pharmacist consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. The consultant shall be a Missouri licensed pharmacist whose license is current and not subject to disciplinary action by the Board. Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall submit a written plan to the Board office outlining what procedures or changes in

operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made. The visits and initial report shall be provided within thirty (30) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Respondent's expense.

H. Consultant shall perform an audit and reconciliation on all controlled substances on a semi-annual basis. The consultant shall report the results of each reconciliation to the Board office.

I. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

J. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order / Agreement.

K. The parties to this Order / Agreement understand that the Board of Pharmacy will maintain this Order / Agreement as an open record of the Board as provided in Chapters 324, 338, 610 RSMo.

2. Upon the expiration of said discipline, Respondent's permit to operate a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided,

however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

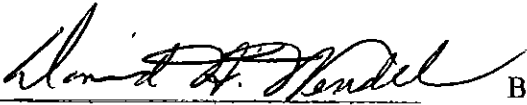
6. Respondent hereby waives and releases the Board, its members and any of its

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

FAMILY ENTERPRISES, INC. d/b/a
SUPER SAVER DISCOUNT PHARMACY

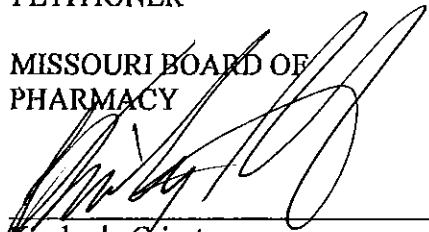
By:


David H. Wendel
President

PETITIONER

MISSOURI BOARD OF
PHARMACY

By:


Kimberly Grinston
Executive Director

Date:


8/9/10

Date:

8-18-10

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